



Comments on the Proposals for Third Party Assessors and TNI

Presented by David Kimbrough,
Ph.D., Chair
May 3, 2017



We would like to thank the Board for this opportunity to present our concerns and we support ELAP's efforts to improve operations implement a uniform accreditation standard in the State.



The ERP is Proposing that All
Laboratory be TNI Compliant and
that ELAP use Third Party Assessors

Coalition of Accredited Laboratories



- CAL represents both Publically Owned and Privately Owned Laboratories, from the Very Large to the Very Small.
 - This is not a “Small Lab” Issue
 - This is not a “Public Lab” Issue
 - TNI and TPAs impact all laboratories

Background



State Board of Health

State of California

Bureau of Sanitary Engineering

34913 3-23 1M

DIRECTIONS FOR EQUIPPING AND OPERATING A SMALL
BACTERIOLOGICAL LABORATORY INTENDED FOR DETERMINING
THE EFFICIENCY OF WATER CHLORINATION.

By W. F. Langelier, Chemist and Bacteriologist.

June 30, 1923.

as of June 14, 1956.

Non-Commercial Laboratories

County and city	Name of laboratory	Date approval given	Determinations covered by Certificate of Approval include			
			Com- plete Bacterio- logical	Cer- tain Bacterio- logical*	Com- plete Chemi- cal	Cer- tain Chemi- cal*
<hr/>						
ALAMEDA						
Oakland	East Bay Muni. Utility Dist., Water Lab, San. and Pumping Section	9-18-52	X		X	
	East Bay Muni. Utility Dist., Lab of Sewage Disp. Div.	5-14-53	X		X	
CONTRA COSTA						
Antioch	Antioch Water Trmt. Plant Lab.	4-21-52	X			X
Oakley	Oakley County Water Dist.	2-21-56	X			X
Pittsburg	Pittsburg Muni. Water Works, Filtration Plant Lab.	1-31-52	X			X
HUMBOLDT						
Eureka	Parkside Lab., City of Eureka	9-22-55	X			X
LOS ANGELES						
Beverly Hills	Beverly Hills Water Dept. Lab	2-18-52	X		X	
Harbor City	County Sanit. Dists. of L.A.	1-16-56	X		X	
Lakewood	Lakewood Water and Power Co. Laboratory	8-17-55	X			
La Verne	F.E. Weymouth Mem. Softening and Filtr. Plant Lab.	4-30-52	X		X	
Los Angeles	L.A. City Dept. of Water and					

Why are Laboratories Accredited?

- *“Reliable laboratory data on water are necessary to ensure a safe water supply and enable the Department of Public Health to carry out its responsibilities...”*
- California Register Vol. 25, No. 2 July 28, 1951

TITLE 17 WATER LABORATORIES
(Register 25, No. 2--7-28-51)

87

Group 6. Water Laboratories

Article 1. Need and Authority for Approval

1174. General Provisions. Reliable laboratory data on water are necessary to ensure a safe water supply and enable the Department of Public Health to carry out its responsibilities as set forth in (a) the Health and Safety Code, Division 1, Part 1, Chapter 2, Article 1, and Division 5, Part 1, Chapter 7, Article 1, and (b) the New Interstate Quarantine Regulations, CFR, Title 42, Chapter 1, Part 12, Subpart D. Data provided by a laboratory other than one operated by a governmental public health agency shall be accepted by a governmental public health agency only when the laboratory has received approval from the Department of Public Health upon an application, as herein provided.

NOTE: Authority cited for Group 6: Health and Safety Code, Division 1, Part 1, Chapter 2, Article 1, and Division 5, Part 1, Chapter 7, Article 1; and the New Interstate Quarantine Regulations, CFR, Title 42, Chapter 1, Part 12, Subpart D.

History: 1. New Group 6 (§§ 1174-1184) filed 7-27-51; effective thirtieth day thereafter (Register 25, No. 2).

What Does ELAP Do?

- Review of Documents submitted by Laboratories
- Review of Results from Performance Testing Samples
- Conduct an On-Site Assessment (OSA)
- Collect a Fee
- Issues a Certificate of Accreditation (or Not)

Environmental Laboratory Accreditation Program Branch (ELAPB)
655 Marina City Parkway, Suite 100, PO Box 340211
Folsom, CA 95624

Application for Certification
Environmental Laboratory Accreditation Program

This application is for laboratories seeking certification under the California Environmental Laboratory Improvement Act (Chapter 6 commencing with Section 186120, Part 1, Chapter 6.01, of the California Health and Safety Code).

PART A
LABORATORY INFORMATION

1. Type of Application	New <input type="checkbox"/> Renewal <input type="checkbox"/> Amendment <input type="checkbox"/>	Certificate No.	14273	Expiration Date	03/31/2015
2. Name of Laboratory	City of Escondido Water Quality Laboratory				
3. Director	Steve and Cheryl				
4. Laboratory Location (Address) (Actual Location)	245 West Main Street				
City	Escondido	State	CA	Zip	92025
5. Laboratory Mailing Address: (For mail delivery)	245 West Main Street				
City	Escondido	State	CA	Zip	92025
6. Laboratory Shipping Address: (For sample delivery)	245 West Main Street				
City	Escondido	State	CA	Zip	92025
7. Telephone # (800, 244, 8111, 1-725)	8. Fax # (800, 244, 8111, 1-725)				
9. E-Mail Address: Boarding@cityofescondido.net	10. Web Site				
11. County (CA only)	San Diego				
12. Where Quality Control Board Region #	3				



This is a Typical Sized Lab testing pH

**Laboratory Director
Quality Manager
Analyst
Dishwasher
Janitor**

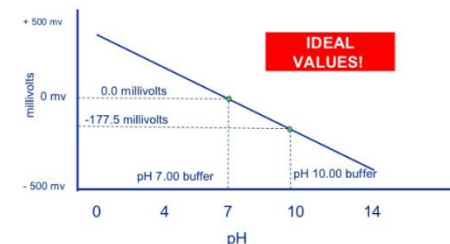


What Does ELAP Look for in an Application and OSA?

- Are there the proper facilities and staff?
- Is there the proper equipment?
- Are there the proper chemicals?
- Are the proper procedures followed?



pH Electrode Calibration Curve



What Does ELAP Look for in PT Samples?

➤ Laboratories Analyze PT Samples

- The Quantity is Unknown
- The Laboratory has to Participate and get the Correct Value
- There are over 700 Labs, 4400 FOTs, Tens of Thousands of Individual Results

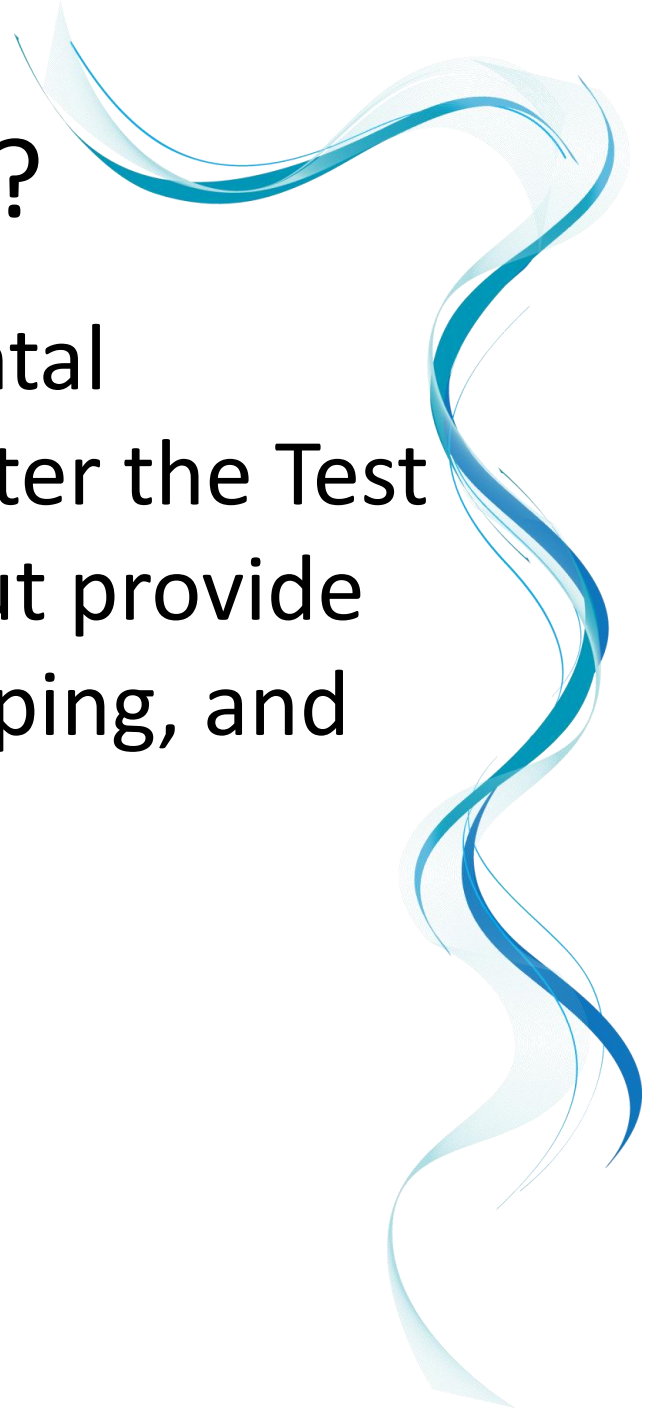


TNI



What is TNI?

It is Collection of Supplemental Requirements that do not alter the Test Methods required by Law but provide additional policy, record keeping, and reporting documentation.



Management Requirements

- **Requirement 4.1.5 c**

Does the laboratory have policies and procedures to ensure the protection of its clients' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results?



Purchasing Requirements

- **Requirement 4.6.2 – 3 - 4**

Does the laboratory ensure that supplies & services comply with specified requirements?



Hundreds of Requirements

Section	Text 1
4.0	Management Requirements
4.1	Organization
4.1.1	The laboratory or the organization of which it is part shall be an entity that can be held legally responsible.
4.1.2	It is the responsibility of the laboratory to carry out its testing and calibration activities in such a way as to meet the requirements of this International Standard and to satisfy the needs of the customer, the regulatory authorities
4.1.3	The management system shall cover work carried out in the laboratory's permanent facilities, at sites away from its permanent facilities, or in associated temporary or mobile facilities.
4.1.4	If the laboratory is part of an organization performing activities other than testing and/or calibration, the responsibilities of key personnel in the organization that have an involvement or influence on the testing and/or calibration are:
4.1.5	The laboratory shall:
4.1.5 a	have managerial and technical personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including the implementation, maintenance and improvement of the
4.1.5 b	have arrangements to ensure that its management and personnel are free from any undue internal and external commercial, financial and other pressures and influences that may adversely affect the quality of their work;
4.1.5 c	have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;
4.1.5 d	have policies and procedures to avoid involvement in any activities that would diminish confidence in its competence, impartiality, judgment or operational integrity;
4.1.5 e	define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;
4.1.5 f	specify the responsibility, authority and interrelationships of all personnel who manage, perform or verify work affecting the quality of the tests and/or calibrations;
4.1.5 g	provide adequate supervision of testing and calibration staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results;
4.1.5 h	have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations;
4.1.5 i	appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the management system related to quality is im
4.1.5 j	appoint deputies for key managerial personnel
4.1.5 k	ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the objectives of the management system.
4.1.6	Top management shall ensure that appropriate communication processes are established within the laboratory and that communication takes place regarding the effectiveness of the management
4.1.7	Additional Requirements for Laboratories
4.1.7.1	Where staffing is limited, the technical manager and the quality manager may be the same person.
4.1.7.1+a	The laboratory's quality manager and/or his/her designee(s) shall:
4.1.7.1 a	serve as the focal point for QNQC and be responsible for the oversight and/or review of QC data;
4.1.7.1 b	have functions independent from laboratory operations for which they have QA oversight;
4.1.7.1 c	be able to evaluate data objectively and perform assessments without outside (e.g., managerial) influence;
4.1.7.1 d	have documented training and/or experience in QA/QC procedures and the laboratory's quality system;
4.1.7.1 e	have a general knowledge of the analytical methods for which data review is performed;
4.1.7.1 f	arrange for or conduct internal audits as per Section 4.14 annually;
4.1.7.1 g	notify laboratory management of deficiencies in the quality system; and
4.1.7.1 h	monitor corrective actions.
4.1.7.2	The laboratory's technical manager(s), however named, and/or his/her designee(s) shall:
4.1.7.2 a	be a member of the staff of an environmental laboratory who exercises actual day-to-day supervision of laboratory operations for the appropriate fields of accreditation and reporting of results;
4.1.7.2 b	be experienced in the fields of accreditation for which the laboratory is seeking accreditation;
4.1.7.2 c	have duties that include:
4.1.7.2 c i	monitoring standards of performance in QC and QA, and
4.1.7.2 c ii	monitoring the validity of the analyses performed and data generated in the laboratory to assure reliable data.
4.1.7.2 d	not be the technical manager(s) of more than one accredited environmental laboratory without authorization from the primary Accreditation Body
4.1.7.2 d+a	Circumstances to be considered in the decision to grant such authorization shall include:
4.1.7.2 d i	the extent to which operating hours of the laboratories to be directed overlap,
4.1.7.2 d ii	adequacy of supervision in each laboratory, and
4.1.7.2 d iii	the availability of environmental laboratory services in the area served.
4.1.7.2 e	if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the technical manager(s) to temporarily perform this function.
4.1.7.2 e+a	If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing; and

For This Lab to Be Accredited for pH TNI Adds

Module 1: 72 Items
Module 2-4: 281 Items
Module 2-5: 352 Items
Module 4: 329 Items
Total: 1,034

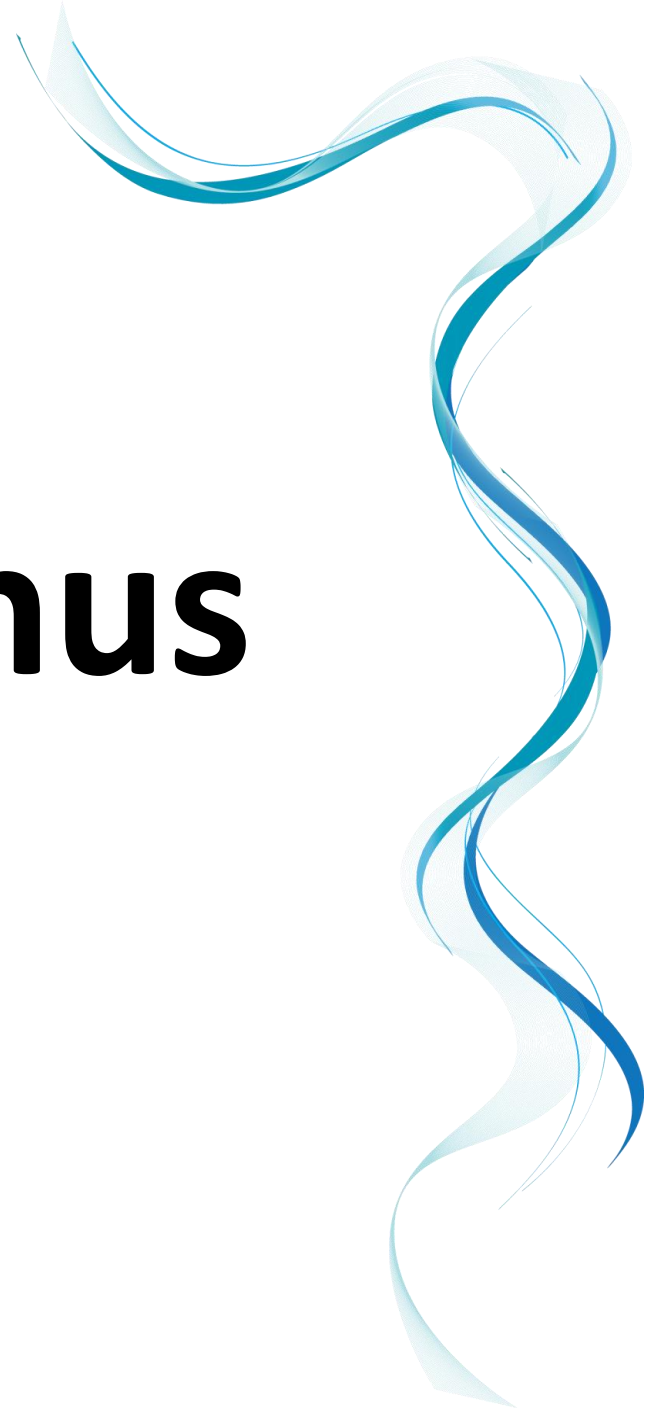


Florida and New York

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Where it has been applied in a compulsory fashion, TNI has resulted in the number of accredited laboratories decreasing, mainly smaller laboratories, both government and private. The costs to all laboratories increased and to the accreditation program.

TNI Minus



Whittling Down

A decorative blue wavy line that starts at the top right, curves around the title, and then flows down the right side of the slide, ending near the bottom right corner.

- *This was discussed at the October 2016 Board Workshop*
 - *We were told that ELAP would “whittle down” the TNI requirements*
 - *We would be working with “TNI Minus” or “TNI Lite”*

TNI Plus



➤ *The Current Proposal from ELAP*

- *Only Deletes Five Items*
- *It adds an Additional 50 or so Items in the form of “Modifications”*
- *However ELAP and the ERP do not want to actually change anything in the TNI documents themselves.*
- *This means the proposal is actually “TNI Plus”*

How Would This Work?



- *TNI is Copyrighted and not Publically Available*
 - *How would this be Incorporated into Regulation?*
 - *How would these Modifications be incorporated if the TNI documents are not to be changed?*
 - *Some Modifications Contradict TNI Requirements*

Third Party Assessors



Why Does ELAP Need TPAs?

- *ELAP's Position is that they are Unable to Conduct OSA's with Current Staff*
 - *ELAP's Authorized Budget and Staff is About the Same Today as in 2001-02*
 - *ELAP Was Able to Conduct OSAs at Close to the Required Frequency of Every Two Years in 2001 – 02*
 - *Why not now?*

HEALTH AND HUMAN SERVICES

HHS 71

1 4260 DEPARTMENT OF HEALTH SERVICES—Continued
2
3
4

	1999-00*	2000-01*	2001-02*
REVENUES AND TRANSFERS			
Revenues:			
125600 Other regulatory fees.....	2,268	2,513	3,445
150300 Income from surplus money investments	84	41	41
Totals, Revenues and Transfers.....	<u>\$2,352</u>	<u>\$2,554</u>	<u>\$3,486</u>
Totals, Resources	<u>\$3,699</u>	<u>\$3,526</u>	<u>\$4,111</u>

3940 State Water Resources Control Board

FUND CONDITION STATEMENTS

	2014-15*	2015-16*	2016-17*
REVENUES, TRANSFERS, AND OTHER ADJUSTMENTS			
Revenues:			
4129200 Other Regulatory Fees	1,708	2,778	3,465
4163000 Investment Income - Surplus Money Investments	<u>2</u>	<u>2</u>	<u>2</u>
Total Revenues, Transfers, and Other Adjustments	<u>\$1,710</u>	<u>\$2,780</u>	<u>\$3,467</u>
Total Resources	\$2,432	\$2,942	\$3,471

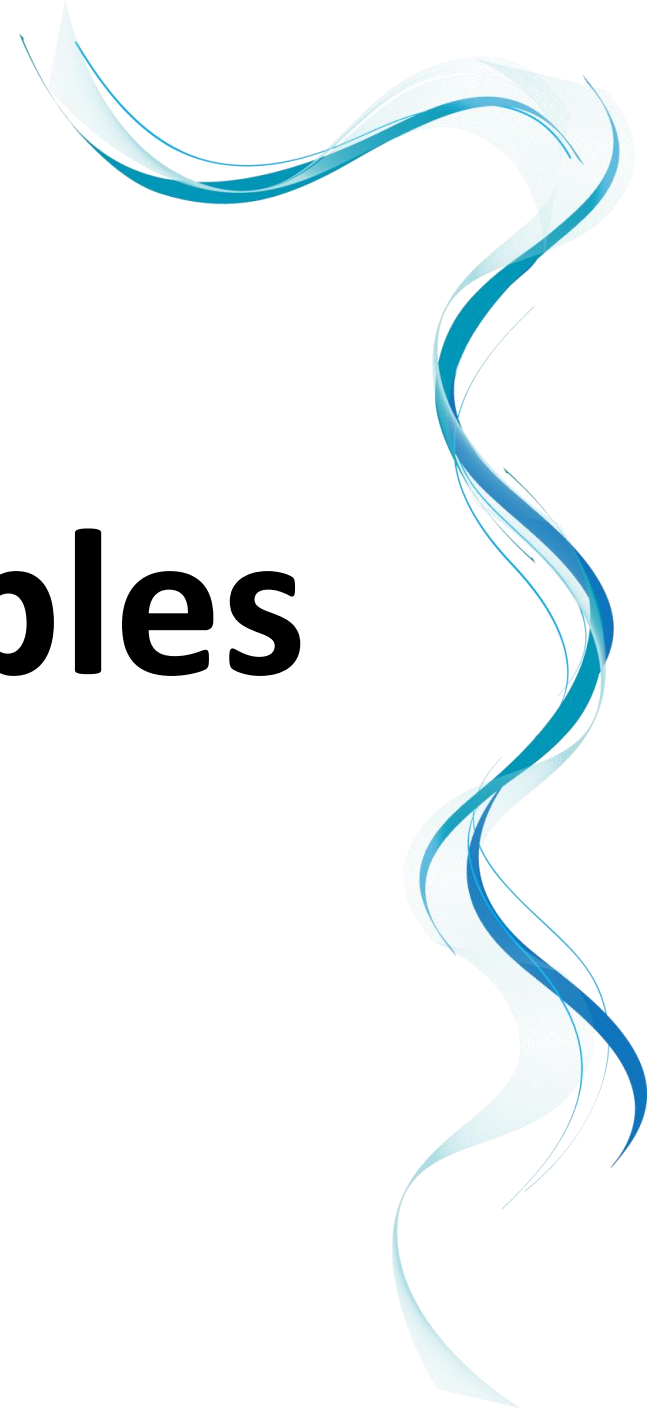
4260 DEPARTMENT OF HEALTH SERVICES—Continued

ORGANIZATIONAL UNIT	NUMBER OF POSITIONS			EXPENDITURES		
	Filled 1999-00	Authorized 2000-01	Proposed 2001-02	Actual 1999-00	Estimated 2000-01	Proposed 2001-02
Classification						
SALARY RANGE						
Environmental Laboratory Accreditation Program:						
Asst Lab Chief-Pub Hlth Lab	1	1	1	5,232-6,324	75,888	75,888
Research Chemist	0.8	1	1	5,228-6,320	63,690	66,873
Research Prog Spec I	1	1	1	4,136-5,027	60,324	60,324
Pub Hlth Chemist III-Supvr	1	1	1	4,139-4,992	59,904	59,904
Pub Hlth Chemist III-Spec ⁷	4.6	6	4	4,136-4,989	355,248	239,472
Microbiologist Spec	1	1	1	4,136-4,989	59,868	59,868
Envimtl Spec III ⁷	1.2	2	1	4,047-4,887	117,288	58,644
Pub Hlth Chemist II ⁷	10.8	14	11	3,764-4,542	712,277	579,690
Staff Svcs Analyst-Gen	1	1	1	2,411-3,805	45,660	45,660
Ofc Techn-Typing	1.7	2	2	2,258-2,745	65,736	65,880
Word Proc Techn	0.2	—	—	1,951-2,546	—	—
Ofc Asst-Typing	1	1	1	1,835-2,370	28,440	28,440
Temporary Help	0.7	—	—	(30,494)	—	—
Overtime	—	—	—	(1,725)	—	—
Totals	26.0	31.0	25.0	\$1,396,009	\$1,644,323	\$1,340,643
Totals, Laboratory Science Division	116.6	160.8	154.3	\$5,506,541	\$7,067,629	\$6,881,113

Why Does ELAP Need TPAs?

- *ELAP has a Long History of being Unable to Adequately Supervise Assessors*
 - *If ELAP Cannot Adequately Supervise their Own Staff, How can they Supervise Contractors and Staff?*
- *If ELAP is Unable to Hire and Retain Adequate Staff, How would Contractors be Able to do so?*

PT Samples



ELAP and PT Samples?

➤ All Laboratories Analyze PT Samples

- There are over 700 Labs, 4400 FOTs, Tens of Thousands of Individual Results
- ELAP is Currently Evaluating PT Samples Manually
- This very inefficient and labor intensive



Fees



Fees

➤ *ELAP Fees Doubled Over the Last 18 Months*

- *This was just to be able to fund ELAP current program*
- *Using TPAs could easily Double Fees again*
- *TNI Requires a Great Deal more Labor for both the Laboratories and ELAP*
- *TNI will drive up fees as well*

Conclusions



What Does ELAP Do?

- Review of Documents submitted by Laboratories?
- ELAP Reviews Performance Testing Samples by Hand
- ELAP Cannot Conduct OSAs
- Issues a Certificate of Accreditation?

Environmental Laboratory Accreditation Program Branch (ELAP)
655 Sierra Sky Parkway, Suite 100, 1st Floor, 94021
Folsom, CA 95624

Application for Certification
Environmental Laboratory Accreditation Program

This application is for laboratories seeking certification under the California Environmental Laboratory Improvement Act (Chapter 6 commencing with Section 186120, Part 1, Chapter 101, of the California Health and Safety Code).

PART A
LABORATORY INFORMATION

1. Type of Application: New [] Renewal [x] Amendment []
Certificate No. 14273 Expiration Date 03/31/2015

2. Name of Laboratory: City of Escondido Water Quality Laboratory

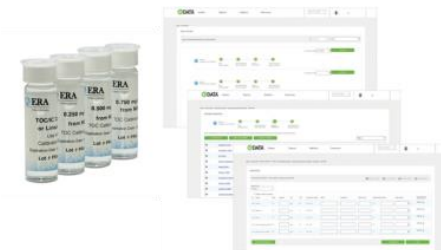
3. Director: Brian Witt

4. Laboratory Location (Address) (Physical Location)
Street: 245 West Main Street
City: Escondido State: CA Zip: 92025

5. Laboratory Mailing Address: (For mail delivery)
Street: 245 West Main Street, Suite 201
City: Escondido State: CA Zip: 92025

6. Laboratory Shipping Address: (For sample delivery)
Street: 245 West Main Street
City: Escondido State: CA Zip: 92025

7. Telephone # 408.244.8111 / 1725
8. Fax # 408.244.8111
9. E-Mail Address: brianwitt@cityofescondido.net
10. Web Site
11. County (CA only) San Diego
12. State Quality Control Board Region # 8



Can ELAP Handle TNI & TPA?

- ELAP is Barely Doing the Minimum Right Now, Even After Doubling our Fees
 - Can they really handle TPAs and TNI?
 - These Proposals can only Result in Much Higher Fees and Less Efficiency
 - Higher Fees and Regulatory Burden will impact the viability of many laboratories